UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

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GRASSO ENTERPRISES, LLC, d/b/a ANNIE'S APOTHECARY, NERxD, LLC, d/b/a CYPRESS COMPOUNDING PHARMACY, and WILEY'S PHARMACY AND COMPOUNDING SERVICES, INC., d/b/a MASON'S PHARMACY,

Plaintiffs,

- against -

EXPRESS SCRIPTS, INC,

Defendant.

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Case No.14-cv-1932(HEA)

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

Plaintiffs Grasso Enterprises, LLC, d/b/a Annie's Apothecary, NERxD, LLC, d/b/a Cypress Compounding Pharmacy, and Wiley's Pharmacy and Compounding Services, Inc., by their attorneys Quadrino Law Group, P.C. and The Simon Law Firm, P.C., for their Complaint against Defendant Express Scripts, Inc., allege as follows:

INTRODUCTION

Express Scripts ("ESI"), the largest claims fiduciary for health plan pharmacy claims in America, has recently embarked upon a scheme to deny all claims under health plans seeking payment for "compound" pharmaceutical medications. Compounded medicines are customized pharmaceuticals made pursuant to specific prescriptions, written by physicians, where no appropriate alternatives are mass-produced or commercially available. Claims for compound medications have, up to now, been routinely paid by ESI directly to in-network compound pharmacies. Each day of every week, month after month, and year after year, ESI has acknowledged that reimbursement for various compound medications are covered and payable under the various group health plans ("Plans") that

ESI administers as the claims administrator and claims fiduciary for these Plans.

According to an internal document prepared by ESI, the goal of its scheme is to cut spending on compound pharmaceuticals by 95%. This marketing and presentation document was predominated by discussion of the spending cuts and how claim denials would be issued stating "Rx 'Not covered' reject".

Notably, the document did not contain a discussion of any changes in scientific findings or studies concerning the efficacy and propriety of prescriptions being filled for these various compound pharmaceutical medications, because no such changes exist. These medications were prescribed by doctors and filled by the pharmacies in accordance with the prescriptions written by those doctors. The various medications have continuously and repeatedly been acknowledged by ESI and the medical community as medically necessary, appropriate, and reimbursable under the Plans, to fill prescriptions that were written to care and treat patients suffering from various medical conditions and ailments. The internal ESI document, also contained no discussion as to the deleterious effects that the withdrawal of these medications will have upon the patients that require them.

The scheme has resulted in the denial of care to thousands of patients, with ongoing harm, as ESI continues to issue unlawful and blanket claim denials that are all in violation of the federal Claims Regulation that governs all group health plan claims in the United States.

By denying the basic ingredients that would permit the compound medications to be made and delivered, ESI is preventing access to healthcare. ESI denies the entirety of each health plan claim, based upon certain ingredients in the compound medications, but there are no alternatives or a different mix of formulations that ESI will approve for payment

on any such claims. Thus ESI is acting in accordance with its stated goal – in its internal document – to nearly end all payments for compounded medications.

The scheme is forcing patients to go without treatment, jeopardizing their health and causing bodily harm, or forcing them to pay out-of-pocket sums that they may or may not be able to afford for basic healthcare needs that have been prescribed by their doctors.

ESI's claim denials do not provide any information whatsoever that would enable a claimant to determine what page or paragraph of what Plan supposedly now states, in either a recent amendment or a new plan year's document, that compound medications are all of a sudden not covered under a written exclusion in the Plan. As more fully delineated herein, either (1) there is indeed existing coverage under the Plans for the compound medications, but those facts are being covered up by ESI, (2) there may have been a Plan amendment that purports to limit or exclude coverage, but ESI has unlawfully withheld information that would allow a review and appeal process as to those denied claims, and / or (3) ESI's decision to deny each claim is either being performed under a discretionary clause in the Plan or in the absence of a discretionary clause, but in either instance making ESI's financially-driven decision either unauthorized, an abuse of discretion, or a breach under the Plans. As such, all of these claim denials can be subject to declaratory and injunctive relief under ERISA, declaring all such decisions, in the absence of full and proper disclosure required by the ERISA Claims Regulation, as unlawful and to be enjoined.

The ERISA Claims Regulation, codified at 29 C.F.R. §2560.503-1 (the "ERISA Claims Regulation" or "Claims Regulation"), governs all group health plan claims in America, both private / commercial plans and all other governmental-employer sponsored

plans, pursuant to ERISA and / or §2719 of the Patient Protection and Affordable Care Act [42 U.S.C. §300gg-19(a)(2)(A)]. The Claims Regulation requires full disclosure as to the specific reasons for each claim denial, along with specific notice provisions and procedural safeguards so that beneficiaries and participants can obtain the required specific information in a timely manner. Having the information enables patients to determine whether the denials can be properly challenged through the mandated ERISA administrative appeals process. Without knowing if their access to medical care is being illegally blocked and not being told that they have options to investigate the truthfulness of the claim denials, patients are searching for alternative means of medical care or foregoing medical care and treatment entirely because they cannot afford the medicines.

The ERISA claims and appeals process, however, outlaws leaving claimants in the dark about their employee benefit plans and claims. It allows claimants to have full and proper notice of the reason(s) for a claim determination and notice that they have access to copies of internal guidelines and / or documents relied upon to make the claim determination, as well as copies of plan documents and ESI's internal emails or data. And each claim denial is required to let claimants know that they have all of these ERISA procedural rights, that they 180 days to pursue an appeal, and that they can resort to the federal courts if an appeal is unsuccessful. These required disclosures and claims procedures are all contained in the Claims Regulation, and they are deemed to be incorporated into all ERISA and non-ERISA group health plans.

In order to cover up its financially-driven scheme, as ESI noted in its internal document, it is issuing intentionally deceptive and misleading letters to patients informing them that there is an unspecified change in their compound medication benefits and that

there is a purported lack of FDA approval for compound medications, which is untrue. The letters suggest that there are safety concerns with regard to compound medications, but the FDA's written guidance and the U.S. Pharmacopeia standards are met regarding the ingredients in compounds, and such compounded medications have been routinely paid for by ESI over the years as medically necessary, efficacious, and properly prescribed by physicians. Thus, the ESI letters are a misleading scare tactic and pretext invented to cover up its true financial goal behind the scheme, as revealed herein.

As discussed in detail below, ESI has not provided any Explanation of Benefits Forms ("EOBs") to Plaintiffs or the patients, as is the industry standard in health plan claims. Instead, ESI has only provided computer-generated boilerplate claim denial notifications to the pharmacies. All such notifications are in violation of the notice and specificity requirements contained in the Claims Regulation. By so doing, ESI has effectively foreclosed any ability that the patients and pharmacies would otherwise have to challenge ESI's determinations. The lack of EOBs and the withholding of all relevant claim information effectively defeats the patients' and the pharmacies' protective safeguards built into, and guaranteed by, the Claims Regulation.

Therefore, this action seeks, *inter alia*: (1) a declaratory judgment under 29 U.S.C. §1132(a)(1)(B) and 28 U.S.C. §2201 that the claim denials are unlawful as not in compliance with the Claims Regulation and that all claims are payable, as a matter of law, in the absence of full, proper, and lawful disclosure because the failure to assert valid defenses and lawfully explain claim decisions renders all such computer-generated blanket claim denials a nullity; (2) pursuant to 29 U.S.C. §1132(a)(3) injunctive relief, ordering ESI to issue ERISA-compliant "Adverse Benefit Determinations," and further ordering that ESI

must continue to render payments for compound medications, unless and until it renders lawfully compliant claim decisions; and (3) a declaratory judgment that ESI must provide a procedure to permit patients to request and gain access to clinically appropriate drugs not covered by the health plan, in accordance with 45 C.F.R. §156.122.

THE PARTIES

1. At all relevant times, Plaintiff Grasso Enterprises, LLC, d/b/a Annie's Apothecary ("Annie's"), was and is a limited liability company organized and existing under the laws of the State of Texas, with a principal place of business located at 31007 IH 10W #108 Boerne, Texas 78006. Annie's is an in-network pharmacy with Express Scripts.

2. At all relevant times, Plaintiff NERxD, LLC, d/b/a Cypress Compounding Pharmacy ("Cypress"), was and is a limited liability company organized and existing under the laws of the State of Texas, with a principal place of business located at 9511 Huffmeister Road, Suite 104, Houston, Texas 77041. Cypress is an in-network pharmacy with Express Scripts.

3. At all relevant times, Plaintiff Wiley's Pharmacy and Compounding Services, Inc., d/b/a Mason's Pharmacy ("Wiley's"), was and is a corporation organized and existing under the laws of the State of Louisiana, with a principal place of business located at 2403 Arkansas Rd., West Monroe, Louisiana 701291. Wiley's is an in-network pharmacy with Express Scripts.

4. At all relevant times, Defendant Express Scripts, Inc. ("ESI"), was and is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business located at One Express Way, St. Louis, Missouri 63121.

JURISDICTION AND VENUE

5. Jurisdiction is founded on 28 U.S.C. §1331 and 29 U.S.C. §1132(e) because a substantial portion of the health plan claims herein arise under the Employee Retirement Income Security Act of 1974 (29 U.S.C. §1001 *et seq*.) ("ERISA") and the regulations promulgated thereunder by the Unites States Department of Labor (29 C.F.R. §2560.503-1). The Department of Labor Claims Regulation, 29 C.F.R. §2560.503-1, has been ratified and expanded to apply to all health plan claims in the United States pursuant to the Patient Protection and Affordable Care Act, 42 U.S.C. §300gg-19(a)(2)(A).

6. Venue is proper in the Eastern District of Missouri pursuant to 28 U.S.C. §§1391(b)(1), (b)(3) and (c), and 29 U.S.C. §1132(e)(2) because Defendant resides in this judicial district, is subject to personal jurisdiction in this judicial district, transacts business in this judicial district, and maintains contacts in this judicial district sufficient to subject it to personal jurisdiction.

COMPOUNDING PHARMACEUTICALS

7. At all relevant times, Plaintiffs were and are compounding pharmacies in the States of Texas and Louisiana. Compounding pharmacies produce customized pharmaceuticals pursuant to specific prescriptions written by physicians, where no appropriate alternatives are mass-produced or commercially available.

8. Compounded medications are prescribed by physicians to treat patients for a wide variety of conditions, diseases and injuries. These medications are used, for example, to treat people struggling with complex syndromes such as diabetic neuropathy, post herpetic neuralgia, and sciatica. Compounds are also prescribed to topically treat major burn and trauma victims, such as injuries to war veterans, who have severe scarring.

These treatments reduce pain and also reduce the number of scar surgeries needed to be performed on these victims. There are compounds used for treating elderly patients in nursing homes with bed sores and pressure wounds that are very difficult to heal. Compounds are also used for hospice patients with fluid restrictions and are they are also vitally important for the treatment of pediatric patients with serious allergies and anaphylactic reactions to ingredients in manufactured medications. In addition to many other uses, Compounded medications are also prescribed by doctors to treat the prevention of pregnancy miscarriages and to treat hormonal conditions and deficiencies.

9. At a time when abuse and addiction to opioid analgesics and narcotics is at historic levels, compounding pharmacists are providing a vital service by giving doctors the tools to treat patients with many topical and alternative medications with no chance of addiction, dependency and abuse.

10. Doctors prescribe compounds because they are the most clinically appropriate therapies for the patient's situation. Doctors receive patient feedback on how the therapies are working and continue to prescribe the formulations that are efficacious and appropriate to improve their patients' lives.

11. For those reasons, among others, compounding pharmacies perform critical and essential services to health care patients, as well as to the communities and geographic areas the pharmacies serve. They provide necessary medicines that are prescribed by doctors for the health of their patients, but that are otherwise unobtainable in the commercial marketplace.

12. Historically, and right up until the recent launching of ESI's scheme, compound medications have been routinely covered and reimbursable under group health

plans.

THE PLANS

13. The plans at issue in this litigation include private employer sponsored Employee Welfare Benefit Plans governed by ERISA, and group health plans of government sponsored employer plans. The ERISA Claims Regulation governs all such plans because the Patient Protection and Affordable Care Act, 42 U.S.C.§300gg-19(a)(2)(A) ("PPACA") expanded the Claims Regulation, promulgated by the United States Department of Labor [codified as 29 C.F.R. §2560.503-1] ("Claims Regulation") from applying to ERISA / private plans to now apply to the claims procedures under all group health plans.

14. Upon information and belief, a substantial number of the Plans at issue in this litigation are Employee Welfare Benefit Plans governed by ERISA[1], and by the Claims Regulation. These ERISA Plans are substantially similar, in their salient features, relevant terms, benefits and conditions, to those of the Plan documents annexed hereto as exhibits "A", "B", "C", and "D".

15. At all relevant times, ESI was and is the Plan Administrator and / or Claims Administrator for the compounding pharmaceutical and prescription drug components of the Plans governing the claims of the patients who sought and are seeking reimbursement under claims filed by Plaintiffs with ESI, under such Plans, in the States of Texas and Louisiana (the "Plans").

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[1]2001 statistics from the Census Bureau and the Department of Labor place the number of Americans insured under ERISA plans at 131 million – an overwhelming majority of the total workforce.

16. The Supreme Court has made clear that health plan claim administrators, when administering plan benefits – as ESI is and has been doing here – can only "administer" claims, as an administrator. A claims administrator, handling claims under a plan, only "manages the plan . . . [and] . . . follows its terms in doing so . . . ." Cigna Corporation v. Amara, 131 S. Ct. 1866 (2011). The Supreme Court explained:

> The plan's sponsor (e.g., the employer), like a trust's settlor, creates the basic terms and conditions of the plan, executes a written instrument containing those terms and conditions, and provides in that instrument "a procedure" for making amendments. §402, 29 U.S.C. §1102. The plan's administrator, a trustee-like fiduciary, manages the plan and follows its terms in doing so . . . . We have found that ERISA carefully distinguishes these roles. See, e.g., Varity Corp., 516 U.S., at 498, 116 S. Ct. 1065. And we have no reason to believe that the statute intends to mix the responsibilities by giving the administrator the power to set plan terms indirectly . . . .

Id. at 1877.

17. As a Plan Administrator and / or Claims Administrator for the ERISA-governed Plans, ESI is a plan "fiduciary" as that term is defined in 29 U.S.C. §1002(21):

> [A] person is a fiduciary with respect to a plan to the extent
>
> (i) he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets,
>
> * * *
>
> (iii) he has any discretionary authority or discretionary responsibility in the administration of such plan.

18. Annexed hereto as Exhibit "D" is a sample ERISA Prescription Drug Benefit Plan managed by ESI for Washington University in St. Louis. Note that the University recognized – and clearly identified – Express Scripts as the ERISA "claim fiduciary" of the

health plan's prescription program:

WASHINGTON UNIVERSITY WELFARE BENEFIT PLAN

Name of Plan: Washington University Welfare Benefit Plan

Name and Address of Plan Sponsor and Named Fiduciary:

Washington University in St. Louis
1 Brookings Drive
St. Louis, MO 63130

The Plan Sponsor retains all fiduciary responsibilities with respect to the Plan except to the extent the Plan Sponsor has delegated or allocated to other persons or entitities one or more fiduciary responsibility with respect to the Plan.

Employer Identification Number (EIN): 43-0653611

IRS Plan Number: 502

Effective Date of Plan: January 1, 2013

Type of Plan: Welfare benefit plan

Name and business address of Plan Administrator:

Plan Sponsor shown above.

Type of Administration of Plan:

The Plan Sponsor provides certain administrative services in connection with its Plan. The Plan Sponsor has contracted with Express Scripts, Inc., One Express Way, St. Louis, MO 63121 for the provision of other administrative services including claims processing services, including coordination of benefit and subrogation; utilization management and complaint resolution assistance.

The named fiduciary of Plan is Washington University, the Plan Sponsor. The Plan Sponsor has also designated Express Scripts, Inc. as the claim fiduciary.

Express Scripts, Inc. shall not be deemed or construed as an employer for any purpose with respect to the administration or provision of benefits under the Plan Sponsor's Plan. Express Scripts, Inc. shall not be responsible for fulfilling any duties or obligation of an employer with respect to the Plan Sponsor's Plan.

19. Attached hereto as Exhibit "A" is a group Plan for the employees and dependents of the University of Texas. ESI is a fiduciary because it has been delegated the discretion to pay or deny claims under the plan. Exhibit "A" at p. 55. This plan governs the claims of Patient "A" who sought and was denied reimbursement in a claim filed on his behalf with ESI by Plaintiff Annie's, as delineated below. The University of Texas Plan indicates, as to coverage for medications that:

> The prescription drug program offers three different benefit levels based on the drug category. Medications on the Express Scripts prescription drug management programs are subject to change. Please refer to the Express Scripts website (www.express-scripts.com/ut) or call Express Scripts Customer Service (1-800-818-0155) for current information on specific medications.

Exhibit "A" at page 50. There is no indication in the plan's terms, however, as to whether the University of Texas, as the employer, would or could make "changes" to the unlisted and unspecified medications or whether the University of Texas has delegated to Express Scripts the authority to purportedly make such "changes".

20. Attached hereto as Exhibit "B" is a group Plan for the employees and dependents of ConocoPhillips. ESI is the named "Claims Administrator" and is a fiduciary because it has been delegated the discretion to pay or deny claims under the plan. Exhibit "B" at pp. B-44, B-49 and B-52. This plan governs the claims of Patient "B" who sought and was denied reimbursement in a claim filed on her behalf with ESI by Plaintiff Cypress, as delineated below. The ConocoPhillips Plan indicates, as to coverage for medications that the Claim Administrator (ESI) has a "preferred drug exclusion list (subject to periodic changes)". Exhibit B. at p. B-53. The plan indicates that a list can be accessed on the employer's website, but there is no indication in the plan's terms as to whether

ConocoPhillips, as the employer, would or could make "changes" to the unlisted and unspecified medications or whether ConocoPhillips has delegated to Express Scripts, as Claim Administrator, the authority to purportedly make such "changes".

21. Attached hereto as Exhibit "C" is a group Plan for the employees and dependents of Louisiana State University System. ESI is a fiduciary under the plan because it has been named as "Pharmacy Benefit Manager" and has been delegated the discretion to pay or deny claims under the plan. Exhibit "C" at p. 82. This plan governs the claims of Patient "C" who sought and was denied reimbursement in a claim filed on his behalf with ESI by Plaintiff Wiley's, as delineated below. The plan has effective dates from January 1, 2014 to December 31, 2014. There is a delineated list of excluded items under the plan's Prescription Drug Benefit, and compounded medicines or their ingredients are not listed as excluded under the plan. Exhibit "C" at p. 66. The plan provides that in the event of an "adverse determination on your claim you will be provided with a written statement that explains the denial and includes instructions on how to appeal that decision." Exhibit "C" at pp. 52 and 55.

22. Upon information and belief, there are ERISA governed Plans that have no provisions granting authority to the Sponsor or Administrator to withdraw from coverage or alter or amend the plan within the plan's one year coverage period. As such, these plans could not be amended – mid-year – to exclude compounded medications or their ingredients. For all patients under ERISA governed Plans that do not permit changes to the plan during its one-year coverage period, they have "vested" prescription benefits.

23. The Washington University in St. Louis plan (Exhibit "D") notes that an independent committee regularly updates a list of medications that are covered

("Formulary"), but those medications are not listed in the plan itself. Exhibit "A" at page 3. Although the plan, with a commencement date of September 1, 2014, indicates that "compound drugs that contain *certain* ingredients *may* not be covered", the plan provides, despite the foregoing ambiguities, that, in keeping with the essential care regulations under the Patient Protection and Affordable Care Act, that "non-covered medications" will be covered if, through an offered exception process, it is shown that the requested drug is medically necessary and essential to the patient's health and that comparable medicines, to the extent any exist, have been unsuccessfully tried (emphasis added).

24. Pursuant to ERISA §404 [29 U.S.C. §1104], as a Plan fiduciary, ESI owes a duty of undivided loyalty to both ERISA Plan participants, their beneficiaries, and statutory beneficiaries, to deal with them in the utmost good faith and to place the interests of Plan participants and beneficiaries above its own interests.

25. 29 U.S.C. §1002(9) defines "person" to include various entities, such as corporations and partnerships.

26. 29 U.S.C. §1002(8) defines an ERISA "beneficiary" as, "a *person* designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit thereunder" (emphasis added).

27. At all times herein, Plaintiffs have provided and supplied, and continue to have patients covered under plans administered by ESI request that they provide and supply, prescribed medically necessary and appropriate compounding pharmaceutical medications to such patients, covered by ERISA Plans administered by ESI.

28. Plaintiffs are ERISA "beneficiar[ies]" pursuant to 29 U.S.C. §1002(8) because they have rights to receive benefits directly, as in-network pharmacy providers, pursuant

to the terms of the applicable ERISA Plans ("Plan-Designated Beneficiary"). See Exhibit "A" at p. 51, Exhibit "B" at p. B-48, B-51-52, and Exhibit "C" at p. 16-18. Indeed, ESI did not pay the patients but rather paid Plaintiffs electronically / directly, as they always do with in-network pharmacies, when they paid the claims of Patients "A", "B", and "C", delineated below.

29. Plaintiffs are also ERISA "beneficiar[ies]" pursuant to 29 U.S.C. §1002(8) because they have been designated to receive benefits by patients, who are participants under the applicable ERISA Plans ("Participant-Designated Beneficiary"). These participants have executed beneficiary designation forms.

30. The benefit designation and assignment forms (the "Benefit Designation Forms") signed by Plaintiffs' patients "A", "B", and "C", participants in the annexed and corresponding Plans "A", "B", and "C" state, in pertinent part, as follows:

> I authorize and designate that payment of any health insurance or medical plan benefits be paid directly to [individual Plaintiff], as beneficiary, for any past, current or future compounds, ingredients, or medications provided to me or my dependents under my / our applicable health insurance or medical plan.

31. These Benefit Designation Forms conferred Participant-Designated Beneficiary status on Plaintiffs. The Benefit Designation Forms used by Plaintiffs were routinely signed by their patients. Sample ["redacted"][2] copies of the Benefit Designation Forms signed by the above three patients / customers of Plaintiffs are attached hereto collectively as Exhibit "E".

32. In addition, the Benefit Designation Forms also contain common law

[2] The patients' names were redacted to protect patient confidentiality under the Health Insurance Portability and Accountability Act ("HIPAA").

assignment language which is separate and apart from the portion of the form that designates the medical provider as a beneficiary in the Participant-Designation section:

> I hereby assign directly to [individual Plaintiff] all rights to payments and other benefits, if any, and all legal and other health plan, ERISA plan, or insurance contract rights that I (or my child, spouse, dependent or minor dependent) may have or had under my / our applicable health plan(s) or health insurance policy(ies) for past, current or future compounds, ingredients, or medications provided. This assignment includes, but is not limited to, a designation that [individual Plaintiff] can act on my / our behalf, as our representative or ERISA representative, as to any initial claim determination, to request any relevant claim or plan documentation or information from the applicable health plan, insurer, or its administrator, to file and pursue appeals to obtain benefits and / or payments that are due or were due to [individual Plaintiff] as a result of compounds, ingredients, or medications provided by [individual Plaintiff]. This assignment and designation also authorizes and designates [individual Plaintiff] to pursue any and all remedies to which I / we may be entitled, including the use of legal action in any court against the health plan, insurer, or its administrator . . . .

See Exhibit "E". Plan participants, and their covered beneficiary spouses, dependents, and/or children who rely on Plaintiffs for their compounding pharmaceutical services, by and through the Benefit Designation Forms, assign their rights to medical benefits to Plaintiffs, rendering Plaintiffs common law assignees, as well as a Participant-Designated Beneficiaries, with the form serving multiple legal purposes.

33. The Benefit Designation Forms also designated Plaintiffs as ERISA representatives of the participants and beneficiaries with respect to their rights to benefits under the ERISA Plans pursuant to 29 C.F.R. §2650.503-1(a)(4). The ERISA representative is yet a fourth, separate and different status to be distinguished from Plan-Designated Beneficiary, Participant-Designated Beneficiary and common law assignee.

34. Plaintiffs are therefore (a) Plan Designated Beneficiaries and Participant Designated Beneficiaries pursuant to 29 U.S.C. §1002(8) and (9), (b) designated ERISA representatives pursuant to 29 C.F.R. §2560.503-1, and / or (c) common law assignees, for their ERISA Plan patients and all non-ERISA Plan patients.

35. To the extent that any ERISA Plan contains an anti-assignment provision, purporting to preclude a plan participant or beneficiary from assigning his or her rights under the plan, any such provision would have no effect upon Plaintiffs' status as a statutory beneficiary pursuant to 29 U.S.C. §1002(8) because ERISA statutorily guarantees the right of a plan or participant to designate a beneficiary, i.e., a Plan-Designated Beneficiary or Participant-Designated Beneficiary. A Plan's Sponsor cannot defeat that right by inserting provisions into an ERISA-governed plan that violate ERISA.

36. To the extent that any patients are covered under plans where a State or the U.S. Government is the employer (such as Federal Employee Health Benefit Act ("FEHBA") claims, applicable to certain federal employees), pursuant to PPACA, all rights under the ERISA Claims Regulation apply to all of those health plans, whether they are group insurance contracts or self insured health plans. Under PPACA §2719, these plans are deemed to incorporate the ERISA Claims Regulations by reference. All references to ERISA Claims Regulation and claims violations therefore apply with equal force to any non-ERISA-governed plans under PPACA.

THE ESI SCHEME

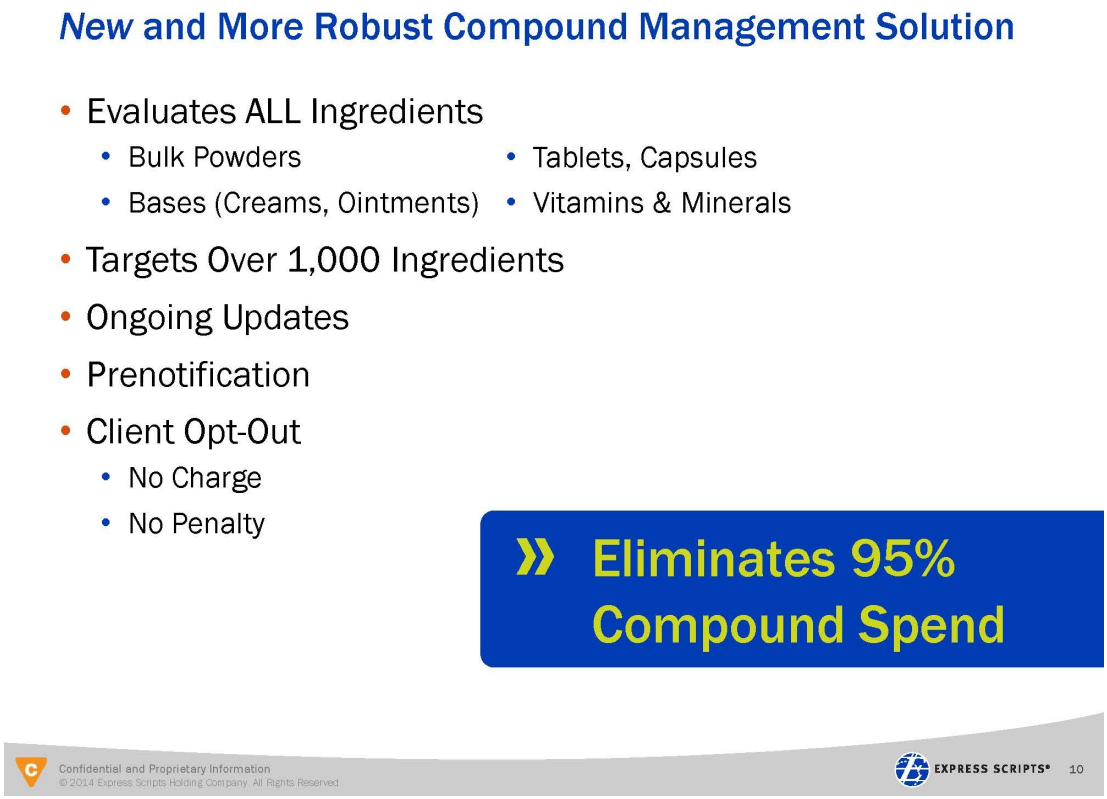
37. Beginning in or about June, 2014, and in direct contravention of its duties as a fiduciary to Plan patients, ESI undertook a scheme to cut spending for compound pharmaceutical costs under the Plans by withdrawing from coverage compound ingredients

necessary and essential for the making of compound pharmaceuticals. The stated objective of ESI was to cut spending; no consideration was given to the health and well-being of the affected Plan participants and their beneficiaries.

38. Indeed, in a PowerPoint presentation to ESI clients dated June 3, 2014, ESI's focus was on costs:

Indeed, the PowerPoint presentation noted that the Express Scripts "Compound Management Solution" would cut spending on compound medications by 95%:

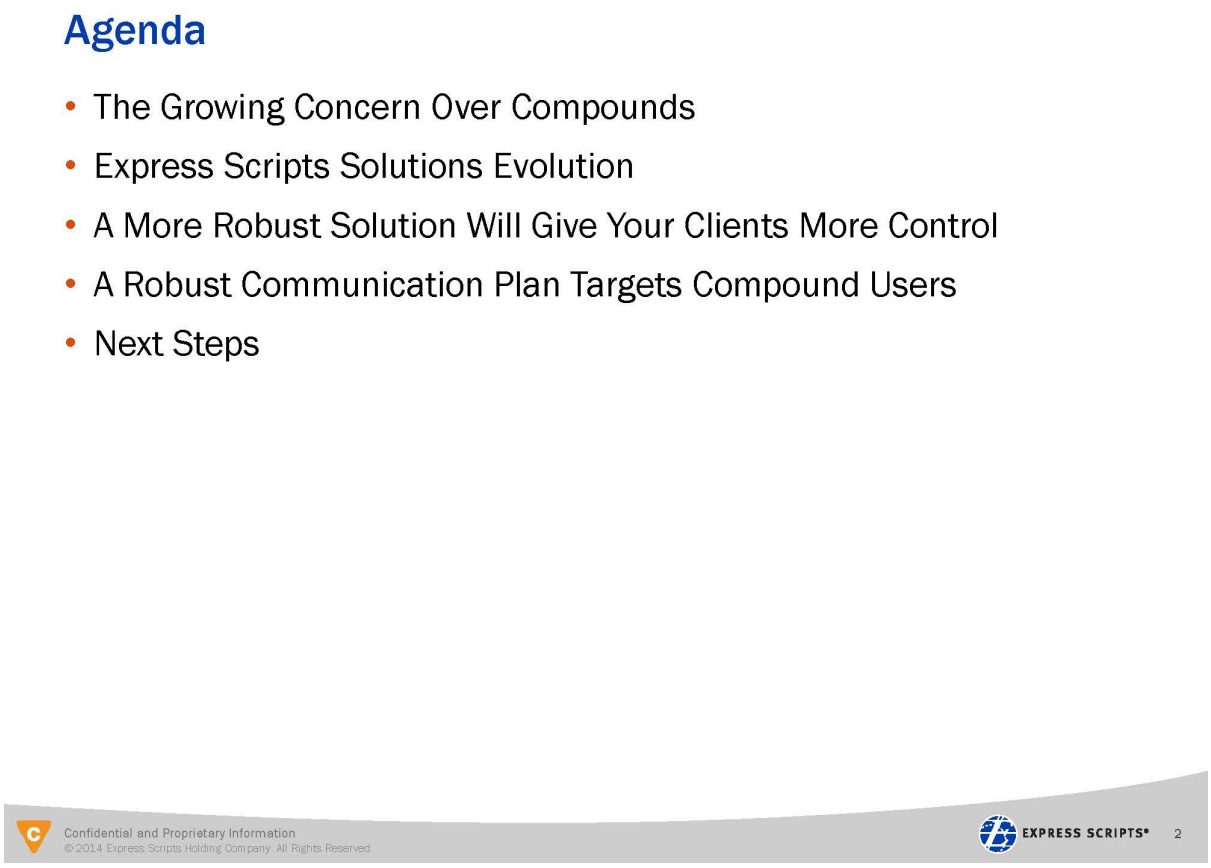
[see next page]



A copy of the ESI Power Point presentation is annexed hereto as Exhibit "F." "Compound Management Solution" is ESI's euphuism for removing coverage for compound medications under the Plans.

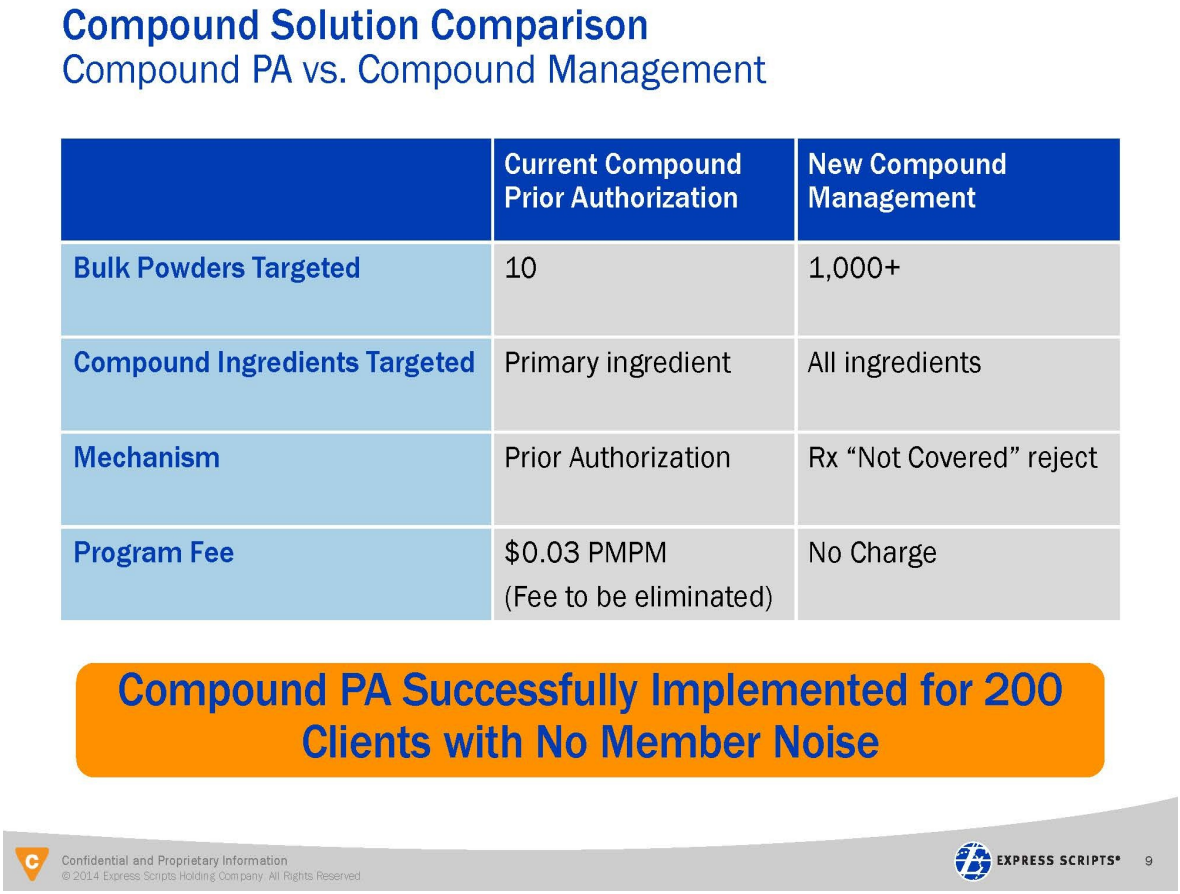
39. Page two of the ESI PowerPoint presentation set forth its "Agenda:"

[see next page]



The "Target" of ESI's "Robust Communication" were the Plan members and beneficiaries that were presently prescribed compound medications and to whom ESI is a fiduciary.

40. Prior to June 2014, ESI floated a trial balloon precursor of its "Compound Management Solution," requiring prior authorization for 10 compounded medicines "targeted" under 200 Plans. ESI reported that the program was successfully implemented, with "No Member Noise:"



Compound Solution Comparison
Compound PA vs. Compound Management

	Current Compound Prior Authorization	New Compound Management
Bulk Powders Targeted	10	1,000+
Compound Ingredients Targeted	Primary ingredient	All ingredients
Mechanism	Prior Authorization	Rx "Not Covered" reject
Program Fee	$0.03 PMPM (Fee to be eliminated)	No Charge

Compound PA Successfully Implemented for 200 Clients with No Member Noise

Exhibit "F" at p. 9.

41. The current proposed "Compound Management Solution" increases the 10 "targeted" compound medications to "1,000+." And critically, it changes the method of rejection from setting up "prior authorization" barriers to simply "'Not Covered' reject," meaning that the compounds will simply be no longer available, regardless of their medical necessity. Id.

42. Although ESI's only focus in its "Compound Management Solution" presentation was to save costs, it sent notifications to some or all of the members, advising

them that their prescriptions were no longer available – not because of the truth, that ESI was implementing a plan to cut spending irrespective of the harm to these members – but rather that they were being discontinued for the members' own safety because "[t]he FDA does not verify the quality, safety and/or effectiveness of compound medications":

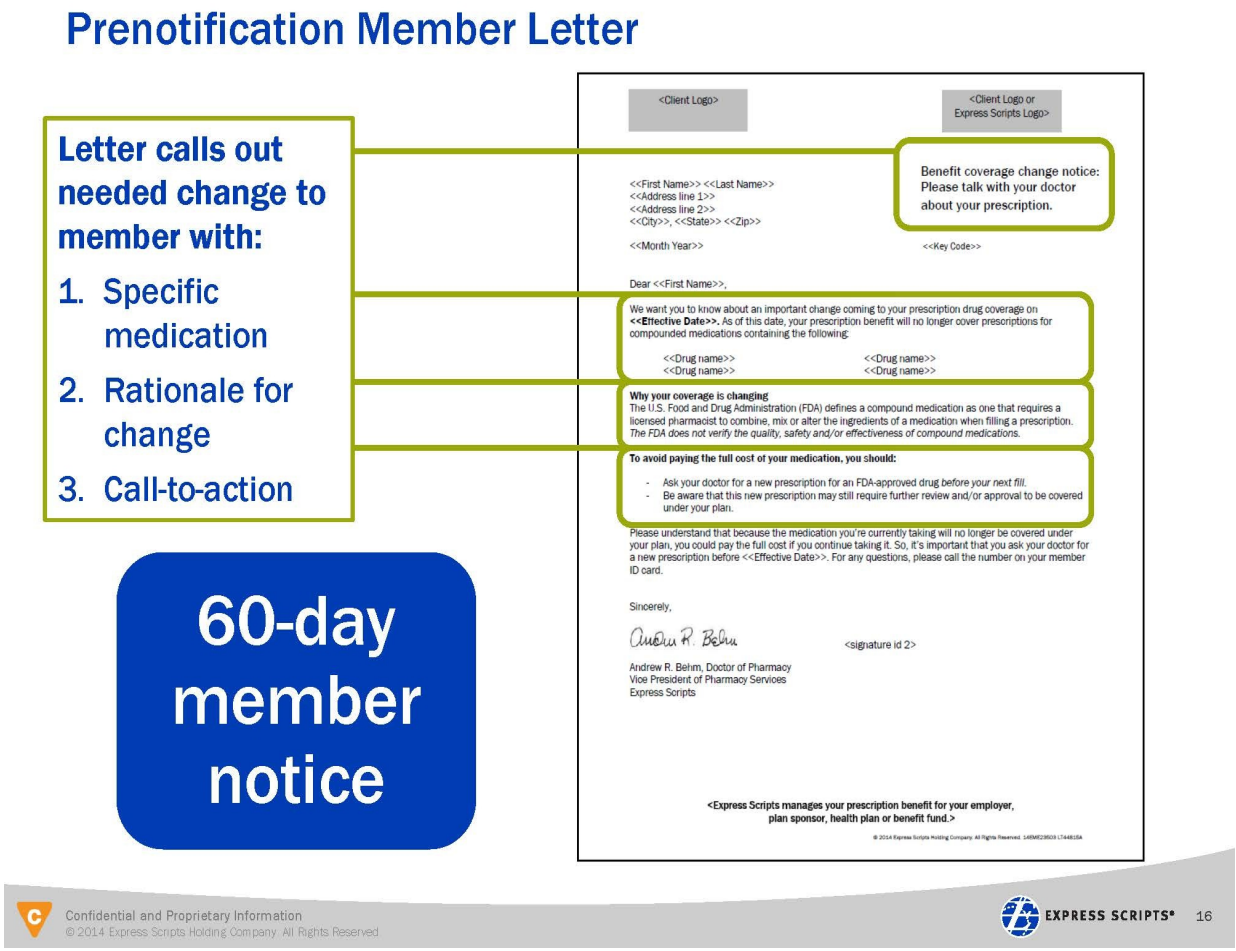


Exhibit "F" at p. 16. A sample of the intentionally deceptive letters sent to the Plan patients incorporating this language and falsely advising of dangers regarding compound medications and not advising that the true reason for the Compound Management Solution was to cut spending – even if patient care was compromised – is annexed hereto as

Exhibit "G". Thus, ESI clearly has implemented the scheme as indicated in Exhibit "F".

ESI's LEGALLY DEFECTIVE AND VOID COMPUTER-GENERATED BOILERPLATE NOTIFICATIONS

43. The ERISA Claims Regulation (29 C.F.R. §2560.503-1) sets forth the *minimum* requirements imposed upon ESI regarding procedures pertaining to claims for benefits from participants, beneficiaries and / or their representatives.

44. The Claims Regulation requires "the plan administrator [to] notify a claimant of the plan's benefit determination" within 30 days, or within a short statutory extension thereof. 29 C.F.R. §2560.503-1. Where the "plan's benefit determination" concerns prescription medications [a "pre-service claim" under 29 C.F.R. §2560.503-1(f)(2)(iii)(A)], the 30-day notification period is reduced to 15 days.

45. A claim denial notification is typically provided through Explanation of Benefits forms ("EOBs"). Upon information and belief, concerning the compounded medications at issue in this litigation, absolutely no EOBs were provided to Plan patients.

46. Instead, Plaintiffs were notified by ESI through computer-generated boilerplate statements of the acceptance or rejection of claims upon their electronic submission of prescriptions. Upon information and belief, all of the computer-generated boilerplate notices from ESI to Plaintiffs are identical or substantially similar in content to those annexed hereto a Exhibits "H", "I", "J", and "K". Upon information and belief, this brief notice to the pharmacy is not followed up with any written notice to the Plan participants or their dependents who seek the Plans' prescription benefits.

47. The Regulation defines "Adverse Benefit Determination" as:

> [A] denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any

> such denial, reduction, or termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item of service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

29 C.F.R. §2560.503-1(m)(4).

48. Pursuant to 29 C.F.R. §2560.503-1(f)(2)(iii)(B), by notifying the Plaintiffs of the adverse benefit determinations, ESI was operating in the capacity of "Plan Administrator", or through a delegation from the employer / groups / sponsors, as Claims Administrator.

49. All of the computer-generated boilerplate notifications denying the claims for compounded drugs after in or about July 2014, constituted "Adverse Benefit Determinations," as that term is defined in 29 C.F.R. §2560.503-1(m)(4).

50. The ERISA Claims Regulation sets forth the legally required content of any Adverse Benefit Determination:

> The notification shall set forth, in a manner calculated to be understood by the claimant –
>
> (i) The specific reason or reasons for the adverse determination;
>
> (ii) Reference to the specific plan provisions on which the determination is based;
>
> (iii) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;
>
> (iv) A description of the plan's review procedures and the time

> limits applicable to such procedures, including a statement of the claimant's rights to bring a civil action under section 502(a) of the Act following an adverse benefits determination on review;
>
> (v) In the case of an adverse benefit determination by a group health plan or a plan providing disability benefits,
>
> > (A) If an internal rule, guideline, protocol, or other similar criteria was relied upon in making the adverse determination, either the specific rule, guideline, protocol or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request; or
> >
> > (B) If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

29 C.F.R. §2560.503-1(g)(emphasis added).

51. The ESI computer-generated boilerplate notifications routinely contain the following or substantially similar language:

> Product/Service Not Covered – Plan Benefit Exclusion (code 70)

52. These computer-generated boilerplate notifications by ESI are all in violation of 29 C.F.R. §2560.503-1 because they:

- Violate 29 C.F.R. §2560.503-1(g)(1)(i) because they fail to identify the specific reason(s) for the adverse determination(s);
- Violate 29 C.F.R. §2560.503-1(g)(1)(ii) because they fail to reference the "specific plan provision(s)" on which the determinations were based;

- Violate 29 C.F.R. §2560.503-1(g)(1)(iii) because they fail to provide "[a] description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary;"

- Violate 29 C.F.R. §2560.503-1(g)(1)(iv) because they fail to provide a description of the plan's review procedures, including the ERISA right to bring a civil action under Section 502(a);

- To the extent that any Adverse Benefit Determination was based on an internal rule, guideline, protocol, or other similar criterion, the computer-generated boilerplate notifications violate 29 C.F.R. §2560.503-1(g)(1)(v)(A) because they fail to identify any specific "internal rule, guideline, protocol, or other similar criterion [that] was relied upon in making the adverse determination," or advise "that a copy of such internal rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request;"

- To the extent that these computer-generated boilerplate notifications can be construed as denials for an alleged lack of medical necessity, they violate 29 C.F.R. §2560-503.1(g)(1)(v)(B), which requires a plan administrator or claims administrator to notify the Plan Participant and / or their beneficiary, "in a manner calculated to be understood by the claimant," "an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances," or advising that "such an explanation [of the scientific or clinical judgment for the determination] will be provided upon request;"

- Violate 29 C.F.R. §2560.503-1(h) because they fail to advise the claimant that they were entitled to be "provided, upon request and free of charge . . . all documents, records, and other information relevant to the claimant's claim for benefits;" and

- Violate 29 C.F.R. §2560.503-1(h) because they fail to advise the claimants that they have one hundred and eighty (180) days following receipt of the notification of

> an Adverse Benefit Determination to appeal the decision.

53. The computer-generated boilerplate notifications by ESI do not indicate who may have altered, amended, or changed the patient's Plan such that something that was covered for an extended period of time is all of a sudden allegedly "not covered". There is no disclosure as to whether the Plan sponsor has made any written change or changes to a Plan or whether ESI, through a delegation, has purported to make or effectuate an alteration, amendment, or change to the Plans or the list of medications included as covered or excluded under the Plans, whether any such delegation of authority exists and, if so, what provision in the Plan would provide such delegation of authority to ESI, from a Plan sponsor.

54. The computer-generated boilerplate notifications by ESI do not indicate when there may have been such an alteration, amendment or change to the Plan such that something that was covered for an extended period of time is all of a sudden allegedly "not covered".

55. The computer-generated boilerplate notifications by ESI do not indicate what document or documents may exist that could have altered, amended, or modified the patient's Plan such that something that was covered for an extended period of time is all of a sudden allegedly "not covered".

56. In the absence of full, lawful, and proper disclosure, Plaintiffs are unable to determine whether there are indeed any lawful, proper, and authorized plan changes or whether the medications are indeed still covered benefits under the Plans. Plaintiffs cannot know, due to the lack of disclosure, whether ESI has exceeded whatever authority

it may have been given as to modifications of lists of approved or excluded medications such that any changes are void and of no legal effect. Moreover, Plaintiffs are unable to determine if there are plan provisions as to "essential benefits" under PPACA, as shown in Exhibit "D", requiring coverage in any event, for essential medicines where there are no alternatives. As of now, there is interruption to patient care and danger to the health of the patient through the elimination of all reimbursement under the guise of a blanket denial entitled "not covered".

57. In the absence of full, lawful, and proper disclosure, Plaintiffs are unable to determine whether they should or could appeal the decision, or what the basis of the appeal would be, or whether it would or would not be meritorious.

58. Upon receipt of ESI's claims denials (Adverse Benefit Determinations), Plaintiffs, as (1) Plan Designated Beneficiaries, (2) Participant Designated Beneficiaries, (3) common law assignees, and (4) ERISA Representatives, were vested with all of the rights and statutory safeguards provided by 29 C.F.R. §2560.503-1, as set forth above, including but not limited to, "[a]ccess to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits." 29 C.F.R. §2560.503-1(h)(2)(iii)(emphasis added).

59. A document, record, or other information will be considered "relevant" to a claimant's claim if such document, record, or other information:

> (i) Was relied upon in making the benefit determination;
>
> * * *
>
> (ii) Was submitted, considered, or generated in the course of making the benefit determination, without regard to whether such document, record, or other information was relied upon

> in making the benefit determination;
>
> * * *
>
> (iii) Demonstrates compliance with the administrative processes and safeguards required pursuant to paragraph (b)(5) of this section in making the benefit determination; or
>
> * * *
>
> (iv) In the case of a group health plan or a plan providing disability benefits, constitutes a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit for the claimant's diagnosis, without regard to whether such advice or statement was relied upon in making the benefit determination.

29 C.F.R. §2560.503-1(m)(8)(i)-(iv)(emphasis added).

60. To the extent that the claims were denied based on ESI's discretion, and not pursuant to a written term or exclusion in a patient's Plan, Express Scripts was required to identify, and provide upon request, among other things, internal emails, memoranda, medical reviews, peer reviewed articles and other studies and/or research materials which were "submitted, considered, or generated in the course of making the benefit determination," which "[d]emonstrate compliance with the administrative processes and safeguards required . . . in making the benefit determination," and which "constitute a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit," and which further identifies:

- the specific reason or reasons for the adverse determination;
- a description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's rights to bring a civil action under section 502(a);

- if an internal rule, guideline, protocol, or other similar criteria was relied upon in making the adverse determination, either the specific rule, guideline, protocol or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request;

- if the adverse benefit determination is based on a medical necessity or experimental treatment, an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

61. To the extent that the claims were denied based on Plan provisions, ESI was required to identify, and provide upon request, among other things, copies of the involved Plan and all documents concerning recent changes and modifications to the Plan (since identical claims were paid in the recent past) and how those changes were introduced and effectuated, including the reasoning therefor and notification thereof to the claimants and how the Plan and its changes were "considered . . . in the course of making the benefit determination," and how the determination was made in "compliance with the administrative processes and safeguards required," and how the changes "constitute a statement of policy or guidance with respect to the plan concerning the denied treatment option or benefit," and which further identifies:

- the specific reason or reasons for the adverse determination;

- a description of the plan's review procedures and the time limits applicable to such procedures, including a statement of the claimant's rights to bring a civil action under section 502(a);

- if an internal rule, guideline, protocol, or other similar criteria was relied upon in making the adverse determination, either the specific rule, guideline, protocol or other similar criterion; or a statement that such a rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination and that a copy of such rule, guideline, protocol, or other criterion will be provided free of charge to the claimant upon request;

- if the adverse benefit determination is based on a medical necessity or experimental treatment, an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

62. In addition to the foregoing, an ERISA Administrator, such as ESI, is required to supply a participant or his or her designee with the Summary Plan Description ("SPD") and, upon written request, a copy of any "[t]rust agreement, contract, or other instruments under which the Plan is established or operated." 29 U.S.C.A. §1021(a)(1) & (2), 29 U.S.C.A. §1024(b)(4).

63. Subsection (b) of the Claims Regulation provides, in pertinent part, that:

> The claims procedures for a plan will be deemed to be reasonable only if . . . [they] comply with the requirements of paragraphs . . . (f), [and] (g) . . . of this section . . . .

64. ESI's adverse benefits determinations do not comply with these sections of the Claims Regulation and are therefore unreasonable as a matter of law and null and void.

65. 29 C.F.R. §2560.503-1(l) provides, in pertinent part:

> In the case of the failure of a plan to establish or follow claims procedures consistent with the requirements of this section, a claimant shall be deemed to have exhausted the administrative

remedies available under the plan . . . .

66. In each circumstance in which the Claims Regulation was violated, the administrative remedies on the claims were deemed exhausted, as a matter of law, pursuant to 29 C.F.R. §2560.503-1(l). In the alternative, any further appeals would have been futile, since ESI is obviously and repeatedly denying all claims for compound pharmaceuticals.

PRESCRIPTION CLAIMS OF PLAINTIFFS' PATIENTS' FILED AND DENIED BY ESI

Annie's Apothecary

67. Patient "A" is and has been an existing patient / customer of Plaintiff Annie's for years. On May 6, 2014, Patient "A" sought a refill of his existing prescription for "Testosterone 15%", and the prescription was routinely refilled. For an example of proof of a recent payment, see Exhibit "H". On September 10, 2014, Patient "A" again sought a refill of the same prescription for "Testosterone 15%", and it was rejected as "Not Covered – Plan/Benefit Exclusion". The computer screen further stated: "Compound Claim Contained at Least One Non-Covered Ingredient". Exhibit "I". However, there was no disclosure to Annie's as to: (1) who allegedly made such a decision to change or modify the Plan's coverage, (2) when any such purported change took place, (3) what documents would show that such a change purportedly occurred, or (4) how to challenge the claim rejection by requesting all relevant documents and data and access to a legally compliant appeals process.

68. Patient "A'" executed a Benefit Designation Form (Exhibit "E"). Patient "A" is a member of the University of Texas Plan (Exhibit "E", first document).

69. Annie's inquired of ESI as to whether any other "ingredient" with which it could make the same type of compound medication delivery system (such as an ointment or salve) was "covered". It was informed by ESI that there was no "covered ingredient" with which it could make a delivery system, which means that Annie's could not provide Patient "A" with the Testosterone in the prescribed form as a covered medication under the Plan. Testosterone is required in high dosages for Patient "A", but it is not commercially manufactured or available in the dosage prescribed by Patient "A's" doctor.

70. Upon information and belief, Patient "A"received no prior notification that his long-standing prescription would be rejected and that coverage would be denied, and no post-denial notification as to why it was denied:

- He received no notice of any change in his Plan;
- He was not advised of the specific reasons for the adverse determination, in violation of 29 C.F.R. §2560.503-1(g)(1)(i);
- He was not advised of the specific plan provision on which the determinations were based, in violation of 29 C.F.R. §2560.503-1(g)(1)(ii);
- He was not advised of the plan's review procedures, including his ERISA right to bring a civil action under Section 502(a), in violation of 29 C.F.R. §2560.503-1(g)(1)(iv);
- He was not informed of any specific "internal rule, guideline, protocol, or other similar criterion [that] was relied upon in making the adverse determination," or advised "that a copy of such internal rule, guideline, protocol, or other criterion will be provided free of charge to [him] upon request," in violation of 29 C.F.R. §2560.503-1(g)(1)(v)(A);
- He was not notified,"in a manner calculated to be understood by [him]," "an explanation of the scientific or

clinical judgment for the determination, applying the terms of the plan to [his] medical circumstances," or advising that "such an explanation [of the scientific or clinical judgment for the determination] will be provided upon request," in violation of 29 C.F.R. §2560-503.1(g)(1)(v)(B);

- He was not advised of his right to be "provided, upon request and free of charge . . . all documents, records, and other information relevant to [his] claim for benefits," in violation of 29 C.F.R. §2560.503-1(h); and

- He was not told that he had one hundred and eighty (180) days following receipt of the notification of an Adverse Benefit Determination (which notification he never received) to appeal the decision, in violation of 29 C.F.R. §2560.503-1(h).

Cypress Compounding Pharmacy

71. Patient "B" is and has been an existing patient / customer of Plaintiff Cypress. On August 7, 2014 and September 11, 2014, Patient "B" sought a refill of an existing prescription for "Estriol/Estradiol (50-50) Progesterone 0.15 MG – .30 MG gel" and the prescription claim was paid for and approved by ESI and filled. See Exhibit "J". On October 9, 2014, Patient "B" sought a refill of the same prescription for "Estriol/Estradiol (50-50) Progesterone 0.15 MG – .30 MG gel" and it was rejected as "Not Covered – Plan/Benefit Exclusion". The computer screen further stated: "Compound Claim Contained at Least One Non-Covered Ingredient". See Exhibit "J". However, there was no disclosure to Cypress as to: (1) who allegedly made such a decision to change or modify the Plan's coverage, (2) when any such purported change took place, (3) what documents would show that such a change purportedly occurred, or (4) how to challenge the claim rejection by requesting all relevant documents and data and access to a legally compliant appeals process.

72. Patient "B'" executed a Benefit Designation Form (Exhibit "E"). Patient "B" is a member of the ConocoPhillips health plan (Exhibit "E", second document).

73. Upon information and belief, Patient "B" received no prior notification that refills of her prescription would be rejected and that coverage would be denied, and no post-denial notification as to why it was denied:

- She received no notice of any change in her Plan;
- She was not advised of the specific reasons for the adverse determination, in violation of 29 C.F.R. §2560.503-1(g)(1)(i);
- She was not advised of the specific plan provision on which the determinations were based, in violation of 29 C.F.R. §2560.503-1(g)(1)(ii);
- She was not advised of the plan's review procedures, including her ERISA right to bring a civil action under Section 502(a), in violation of 29 C.F.R. §2560.503-1(g)(1)(iv);
- She was not informed of any specific "internal rule, guideline, protocol, or other similar criterion [that] was relied upon in making the adverse determination," or advised "that a copy of such internal rule, guideline, protocol, or other criterion will be provided free of charge to [her] upon request," in violation of 29 C.F.R. §2560.503-1(g)(1)(v)(A);
- She was not notified,"in a manner calculated to be understood by [her]," "an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to [her] medical circumstances," or advising that "such an explanation [of the scientific or clinical judgment for the determination] will be provided upon request," in violation of 29 C.F.R. §2560-503.1(g)(1)(v)(B);
- She was not advised of her right to be "provided, upon request and free of charge . . . all documents, records, and other information relevant to [her] claim for

benefits," in violation of 29 C.F.R. §2560.503-1(h); and

- She was not told that she had one hundred and eighty (180) days following receipt of the notification of an Adverse Benefit Determination (which notification she never received) to appeal the decision, in violation of 29 C.F.R. §2560.503-1(h).

Wiley's Pharmacy and Compounding

74. Patient "C" is and has been an existing patient/customer of Plaintiff Wiley's. On August 14, 2014, September 10, 2014, and September 20, 2014, Patient "C" sought a refill of his existing prescription for "Diethylstilbestrol, 1 MG", for prostate cancer treatment, and the prescription claims were approved and paid for by ESI and the prescription was filled on each date. On September 26, 2014, Patient "C" sought a refill of the same prescription for "Diethylstilbestrol 1 MG", and it was rejected as "Not Covered – Plan/Benefit Exclusion". The computer screen further stated: "Compound Claim Contained at Least One Non-Covered Ingredient." See Exhibit "K". However, there was no disclosure to Wiley's as to: (1) who allegedly made such a decision to change or modify the Plan's coverage, (2) when any such purported change took place, (3) what documents would show that such a change purportedly occurred, or (4) how to challenge the claim rejection by requesting all relevant documents and data and access to a legally compliant appeals process.

75. Patient "C'" executed a Benefit Designation Form (Exhibit "E"). Patient "C" is a member of the Louisiana State University System health plan (Exhibit "E", third document).

76. Upon information and belief, Patient "C" received no notification that his prescription would be rejected and that coverage would be denied, and no post-denial

notification as to why it was denied:

- He received no notice of any change in his Plan;
- He was not advised of the specific reasons for the adverse determination, in violation of 29 C.F.R. §2560.503-1(g)(1)(i);
- He was not advised of the specific plan provision on which the determinations were based, in violation of 29 C.F.R. §2560.503-1(g)(1)(ii);
- He was not advised of the plan's review procedures, including his ERISA right to bring a civil action under Section 502(a), in violation of 29 C.F.R. §2560.503-1(g)(1)(iv);
- He was not informed of any specific "internal rule, guideline, protocol, or other similar criterion [that] was relied upon in making the adverse determination," or advised "that a copy of such internal rule, guideline, protocol, or other criterion will be provided free of charge to [him] upon request," in violation of 29 C.F.R. §2560.503-1(g)(1)(v)(A);
- He was not notified,"in a manner calculated to be understood by [him]," "an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to [his] medical circumstances," or advising that "such an explanation [of the scientific or clinical judgment for the determination] will be provided upon request," in violation of 29 C.F.R. §2560-503.1(g)(1)(v)(B);
- He was not advised of his right to be "provided, upon request and free of charge . . . all documents, records, and other information relevant to [his] claim for benefits," in violation of 29 C.F.R. §2560.503-1(h); and
- He was not told that he had one hundred and eighty (180) days following receipt of the notification of an Adverse Benefit Determination (which notification he never received) to appeal the decision, in violation of 29 C.F.R. §2560.503-1(h).

In addition, contrary to the provisions of the Claims Regulation and in violation of the terms of the plan at page 55, neither Patient "C" nor Wiley's received a "written statement that explains the denial and . . . instructions on how to appeal that decision."

COUNT ONE

(29 U.S.C. §1132(a)(1)(B): For Declaratory Relief)

77. Plaintiffs repeat verbatim and incorporate by reference herein Paragraphs "1" through "76" above.

78. ESI has violated and ignored each and every provision contained in the Claims Regulation.

79. As of this date, ESI continues to unlawfully deny claims for compounded medications submitted by Plaintiffs for Plan patients.

80. ESI's violations of the ERISA Claims Regulations and failure to assert proper and specific grounds for non-payment are a waiver, as a matter of law, of all potential defenses to payment.

81. Upon information and belief, ESI has denied claims for "vested" benefits, in violation of ERISA.

82. Due to the foregoing, Plaintiffs are entitled to a declaratory judgment under 29 U.S.C. §1132(a)(1)(B) and 28 U.S.C. §2201 that the claim decisions are unlawful as not in compliance with the Claims Regulation and that all claims for compound medications are payable, as a matter of law, in the absence of full, proper, and lawful disclosure because the failure to assert valid defenses and lawfully explain claim decisions renders all such computer-generated blanket claim denials a nullity. In addition, Plaintiffs are entitled to a

declaratory judgment that all vested benefits are payable, regardless of the foregoing.

83. Due to the foregoing, Plaintiffs are further entitled to a declaration that on all future claims filed by Plaintiffs on behalf of participants and beneficiaries covered under any Plan, ESI must issue ERISA-compliant "Adverse Benefit Determinations," and further ordering that ESI must continue to render payments for all such compound medications, unless and until it renders lawfully compliant claim decisions in accordance with 29 C.F.R. §2560.503.1. In addition, Plaintiffs are entitled to a declaratory judgment that all vested benefits are payable, regardless of the foregoing.

COUNT TWO

(29 U.S.C. §1132(a)(3): Injunctive Relief)

84. Plaintiffs repeat verbatim and incorporate by reference herein Paragraphs "1" through "83" above.

85. ESI has violated and ignored each and every provision contained in the Claims Regulation.

86. As of this date, ESI continues to deny claims for compounded medications submitted by Plaintiffs for Plan patients.

87. Plan patients whose claims for prescribed compounded medications are denied suffer immediate and irreparable harm by being deprived of the medicine needed to make them well, or to ease their suffering, or to relieve their pain, or to help them heal, or to prevent their medical problems from worsening, or to improve or restore their health.

88. Plan patients whose claims for prescribed compounded medications are denied suffer immediate and irreparable harm by being deprived of the federally mandated safeguards and protections guaranteed to them by the Claims Regulation.

89. Plaintiffs suffer immediate and irreparable harm because their only business is as a compound pharmacy. ESI's scheme will quickly put Plaintiffs out of business.

90. Plaintiffs additionally suffer immediate and irreparable harm from the untrue and deceptive letters being sent by ESI to Plan members falsely suggesting that the reason compound drugs are being denied is because they are unsafe and not FDA approved. Such false statements will tarnish Plaintiffs' reputation and affect and destroy their good will and business relationships built up over years with their patient/customers. Such loss cannot accurately be monetarily quantified, and is therefore irreparable.

91. There is, moreover, doubt whether Plaintiffs legally can even obtain damages in the form of lost profits. The remedies under ERISA § 502(a)(3) [29 U.S.C. § 1132(a)(3)] do not include such monetary damages. If money damages are legally unavailable, they are not an adequate remedy at law.

92. Due to the foregoing, the Court should order ESI to issue ERISA-compliant "Adverse Benefit Determinations," and further order that ESI must continue to render payments for compound medications, unless and until it renders lawfully compliant claim decisions in conformance with the provisions of the ERISA Claims Regulation.

93. In addition, Plaintiffs are entitled to a preliminary injunction that prohibits the withholding by ESI of all vested benefits, regardless of the foregoing.

COUNT THREE

(42 U.S.C. §300gg-6; 45 C.F.R. §156.122;
28 U.S.C. §2201; For Declaratory Relief)

94. Plaintiffs repeat verbatim and incorporate by reference herein Paragraphs "1" through "93" above.

95. As of January 1, 2015, all qualified health plans under PPACA are required to offer and provide "Essential Health Benefits" pursuant to 42 U.S.C. §300gg-6 for plans that are within the purview of that section.

96. "Essential Health Benefits" includes coverage for "Prescription Drugs" under 42 U.S.C. §18022(b)(1)(F).

97. 45 C.F.R. §156.122, promulgated under PPACA states, in pertinent part:

> (c) A health plan providing essential health benefits must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan.

98. Upon information and belief, ESI does not provide a procedure whereby patients can request and gain access to clinically appropriate drugs not covered by the health plan.

99. Due to the foregoing, Plaintiffs are entitled to a declaratory judgment that ESI must provide a procedure to permit patients to request and gain access to clinically appropriate drugs not covered by the health plan.

WHEREFORE, Plaintiffs Grasso Enterprises, LLC, d/b/a Annie's Apothecary, NERxD, LLC, d/b/a Cypress Compounding Pharmacy, and Wiley's Pharmacy and Compounding Services, Inc., demand judgment, in their favor and against Defendant Express Scripts, Inc.:

A. On the First Cause of Action, for a declaratory judgment under 29 U.S.C. §1132(a)(1)(B) and 28 U.S.C. §2201:

(1) that the claim decisions are unlawful as not in compliance with the Claims Regulation and that all claims for compound medications are payable, as a matter of law,

in the absence of full, proper, and lawful disclosure because the failure to assert valid defenses and lawfully explain claim decisions renders all such computer-generated blanket claim denials a nullity; in addition, Plaintiffs are entitled to a declaratory judgment that all vested benefits are payable, regardless of the foregoing.

(2) that on all future claims filed by Plaintiffs on behalf of participants and beneficiaries covered under any Plan, ESI must issue ERISA-compliant "Adverse Benefit Determinations," and further ordering that ESI must continue to render payments for all such compound medications, unless and until it renders lawfully compliant claim decisions in accordance with 29 C.F.R. §2560.503.1; and

(3) that all vested benefits are payable, regardless of the foregoing.

B. On the Second Cause of Action, for an injunction pursuant to 29 U.S.C. §1132(a)(3), and 29 U.S.C. §2201:

(1) ordering ESI to issue ERISA-compliant "Adverse Benefit Determinations," and further ordering that ESI must continue to render payments for all such compound medications, unless and until it renders lawfully compliant claim decisions in conformance with the provisions of the ERISA Claims Regulation; and

(2) for a preliminary injunction that prohibits the withholding by ESI of all vested benefits, regardless of the foregoing.

C. On the Third Cause of Action, for a declaratory judgment pursuant to 28 U.S.C. §2201, ordering that ESI must provide a procedure pursuant to 42 U.S.C. §300gg-6 and 45 C.F.R. §156.122, to permit patients to request and gain access to clinically appropriate drugs not covered by the health plan; and

D. For such other, further and different relief as the Court deems just and

proper, including but not limited to an order declaring that because Plaintiffs have achieved "some success on the merits", ESI must pay to Plaintiffs the ERISA statutorily authorized legal fees for this matter.

Dated: Melville, New York
January 8, 2015

QUADRINO LAW GROUP, P.C.

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